



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

SEP - 3 2008

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

Olympus America Inc.  
c/o Ms. Stephanie Donnelly  
Regulatory Affairs/Quality Assurance Manager  
3131 West Royal Lane  
Irving, TX 75063

Re: k080094  
Trade/Device Name: Olympus Total  $\beta$ hCG Test System  
Regulation Number: 21 CFR 862.1155  
Regulation Name: Human chorionic gonadotropin test system  
Regulatory Class: Class II  
Product Code: DHA, JIT, JJX  
Dated: July 23, 2008  
Received: July 28, 2008

Dear Ms. Donnelly:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

*Jean M. Cooper, M.S., D.V.M.*

Jean M. Cooper, M.S., D.V.M.

Director

Division of Chemistry and Toxicology

Office of *In Vitro* Diagnostic Device

Evaluation and Safety

Center for Devices and

Radiological Health

Enclosure

## Indication for Use

510(k) Number (if known): K080094

Device Name: The Olympus Total  $\beta$ hCG Test System (OS210303).

The Olympus  $\beta$ hCG assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of total beta human chorionic gonadotropin (intact  $\beta$ hCG and free  $\beta$ ) levels in human serum using the Olympus AU3000i Immunoassay System. Total  $\beta$ hCG is used for the early detection of pregnancy. For in vitro diagnostic use only.

The Olympus  $\beta$ hCG Calibrator is for calibrating the quantitative Olympus  $\beta$ hCG assay on the Olympus AU3000i Immunoassay System.

The Olympus  $\beta$ hCG Control is used for quality control of the Olympus  $\beta$ hCG assay on the Olympus AU3000i Immunoassay System.

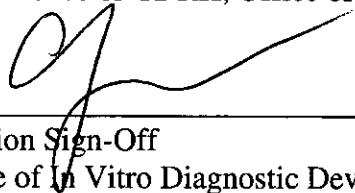
Prescription Use ✓  
(21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use \_\_\_\_  
(21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

  
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Division Sign-Off  
Office of In Vitro Diagnostic Device  
Evaluation and Safety

510(k) K080094